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L6: Entry 1 of 1 File: DWPI Aug 15, 2002

DERWENT-ACC-NO: 2002-130834
DERWENT-WEEK: 200256

TITLE: Treating human papilloma virus infection, in a subject, involves administering a fusion protein comprising a protein of HPV which is different from the type of HPV that causes the disease or condition

INVENTOR: BOUX, L J; GOLDSTONE, S E ; NEEFE, J R ; SIEGEL, M ; WINNETT, M T ; GOLDSTONE, S ; NEEFE, J ; WINNETT, M

PRIORITY-DATA: 2000US-214202P (June 26, 2000), 2001US-0891823 (June 26, 2001)

PATENT-FAMILY:

PUB-NO	PUB-DATE	LANGUAGE	PAGES	MAIN-IPC
US 20020110566 A1	August 15, 2002		000	A61K039/12
WO 200200242 A2	January 3, 2002	E	034	A61K038/00
AU 200171449 A	January 8, 2002		000	A61K038/00

INT-CL (IPC): A61 K 38/00; A61 K 39/12

ABSTRACTED-PUB-NO: US20020110566A
BASIC-ABSTRACT:

NOVELTY - Treating (M1) a disease or condition associated with a human papilloma virus (HPV) infection, in a subject, comprising administering a fusion protein (I) of a protein of HPV which is different from the type of HPV that causes the disease or condition, or administering a nucleic acid encoding (I), is new.

DETAILED DESCRIPTION - Treating (M1) a disease or condition associated with a human papilloma virus (HPV) infection, in a subject, comprising:

(a) treating a wart in a subject, by identifying a subject having or suspected of having a wart, and administering a composition (C1) comprising a fusion protein (I) comprising a heat shock protein (hsp) or its immunostimulatory fragment, and a protein of HPV or its antigenic fragment, or a nucleic acid (II) encoding (I); or

(b) treating a disease or condition associated with HPV, in a

subject, by administering (C2) comprising hsp or its immunostimulatory fragment, and a protein (or its antigenic fragment) of HPV of first type, to the subject, where the subject is infected with an HPV type that is different from the HPV type administered to the subject, or a nucleic acid encoding (I).

INDEPENDENT CLAIMS are also included for the following:

(1) use of C1 in the manufacture of a medicament for the treatment of a wart;

(2) use of C2 in the manufacture of a medicament for the treatment of an infection by HPV of a second type, where the first type and second type are different; and

(3) use of (II) in the manufacture of a medicament for the treatment of a wart, or in the manufacture of a medicament for the treatment of an infection by HPV of a second type, where the first type and second type are different.

ACTIVITY - Dermatological; virucide; cytostatic.

22 patients participated in a randomized, double-blind, placebo-controlled, multicenter trial of HspE7 (fusion protein containing Mycobacterium bovis BCG Hsp65 coupled to E7 protein of HPV type 16) in the treatment of anal high-grade squamous intraepithelial lesions (HSIL). Patients were typed for HPV using cells obtained from an anal swab, but were not required to have HPV-16. Individual lesions were not types for HPV. Patients received 3 subcutaneous injections of 100 micro g of HspE7 or placebo at monthly intervals. They were assessed for treatment response by anal Pap smears, high-resolution anoscopy (HRA) with biopsy, and global physical assessment. Non-responders (i.e. those with persistent anal HSIL) after 12 or 24 weeks in the controlled trial were allowed to crossover to an open-label trial where they received 3 injections of 500 micro g of HspE7 at monthly intervals. The treatment assignment was double-blinded in the placebo-controlled trial, and the blind has not been broken. At the time of their entry into the open label trial, 14 of the 22 patients (64 %) had anogenital warts that had persisted throughout the prior double-blind trial in which they received 3 monthly injections of 100 micro g of HspE7 or placebo. Of the 14 patients, 8 patients (57 %) had worsened, 4 patients (29 %) had no change, and 2 patients (14 %) improved (one dramatically and the other minimally) by the time they crossed over to the open label trial. Of the 14 patients with warts at the beginning of the open label trial, the site investigator determined that surgical ablation was needed for 11 (79 %) patients, local ablation was needed for 2 patients (14 %), and topical treatment was needed for 1 patient (7 %). These patients elected to postpone the site investigator's recommended treatment, consenting instead to receive 3 injections of HspE7 500 micro g monthly intervals in the open label trial. One month after the final treatment with 500 micro g of HspE7, 2 patients (14 %) had no detectable warts, 11 patients (79 %) had a reduction in the size or number of warts as compared with their status upon entry into the open-label trial, and 1 patient (7 %) experienced an increase in wart size. By the time of the primary

evaluation point of the open label trial (4 months after the final dose) one additional patient experienced an improvement from partial to complete response (i.e. no visible warts), giving a total of 3 (21 %) complete responders. None of these responders relapsed during 6 months of evaluation in the open label trial. 10 patients (71 %) continued to exhibit improvement in partial response (i.e. warts reduced further in size significantly with continued diminution of the extent of treatment needed to remove the remaining warts). The one non-responder (97 %) did not improve by the end of the open-label trial.

MECHANISM OF ACTION - Vaccine.

USE - (I) and (II) are useful for treating a wart, and a disease or condition associated with HPV, e.g. anogenital warts, plantars warts, cervical cancer, cervical dysplasia, anal cancer anal dysplasia, or recurrent respiratory papillomatosis.

ABSTRACTED-PUB-NO:

WO 200200242A
EQUIVALENT-ABSTRACTS:

NOVELTY - Treating (M1) a disease or condition associated with a human papilloma virus (HPV) infection, in a subject, comprising administering a fusion protein (I) of a protein of HPV which is different from the type of HPV that causes the disease or condition, or administering a nucleic acid encoding (I), is new.

DETAILED DESCRIPTION - Treating (M1) a disease or condition associated with a human papilloma virus (HPV) infection, in a subject, comprising:

(a) treating a wart in a subject, by identifying a subject having or suspected of having a wart, and administering a composition (C1) comprising a fusion protein (I) comprising a heat shock protein (hsp) or its immunostimulatory fragment, and a protein of HPV or its antigenic fragment, or a nucleic acid (II) encoding (I); or

(b) treating a disease or condition associated with HPV, in a subject, by administering (C2) comprising hsp or its immunostimulatory fragment, and a protein (or its antigenic fragment) of HPV of first type, to the subject, where the subject is infected with an HPV type that is different from the HPV type administered to the subject, or a nucleic acid encoding (I).

INDEPENDENT CLAIMS are also included for the following:

(1) use of C1 in the manufacture of a medicament for the treatment of a wart;

(2) use of C2 in the manufacture of a medicament for the treatment of an infection by HPV of a second type, where the first type and second type are different; and

(3) use of (II) in the manufacture of a medicament for the

treatment of a wart, or in the manufacture of a medicament for the treatment of an infection by HPV of a second type, where the first type and second type are different.

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MECHANISM OF ACTION - Vaccine.

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dysplasia, or recurrent respiratory papillomatosis.

ABSTRACTED-PUB-NO: US20020110566A
EQUIVALENT-ABSTRACTS: NOVELTY - Treating (M1) a disease or condition associated with a human papilloma virus (HPV) infection, in a subject, comprising administering a fusion protein (I) of a protein of HPV which is different from the type of HPV that causes the disease or condition, or administering a nucleic acid encoding (I), is new. DETAILED DESCRIPTION - Treating (M1) a disease or condition associated with a human papilloma virus (HPV) infection, in a subject, comprising: (a) treating a wart in a subject, by identifying a subject having or suspected of having a wart, and administering a composition (C1) comprising a fusion protein (I) comprising a heat shock protein (hsp) or its immunostimulatory fragment, and a protein of HPV or its antigenic fragment, or a nucleic acid (II) encoding (I); or (b) treating a disease or condition associated with HPV, in a subject, by administering (C2) comprising hsp or its immunostimulatory fragment, and a protein (or its antigenic fragment) of HPV of first type, to the subject, where the subject is infected with an HPV type that is different from the HPV type administered to the subject, or a nucleic acid encoding (I). INDEPENDENT CLAIMS are also included for the following: (1) use of C1 in the manufacture of a medicament for the treatment of a wart; (2) use of C2 in the manufacture of a medicament for the treatment of an infection by HPV of a second type, where the first type and second type are different; and (3) use of (II) in the manufacture of a medicament for the treatment of a wart, or in the manufacture of a medicament for the treatment of an infection by HPV of a second type, where the first type and second type are different. ACTIVITY - Dermatological; virucide; cytostatic. 22 patients participated in a randomized, double-blind, placebo-controlled, multicenter trial of HspE7 (fusion protein containing Mycobacterium bovis BCG Hsp65 coupled to E7 protein of HPV type 16) in the treatment of anal high-grade squamous intraepithelial lesions (HSIL). Patients were typed for HPV using cells obtained from an anal swab, but were not required to have HPV-16. Individual lesions were not types for HPV. Patients received 3 subcutaneous injections of 100 micro g of HspE7 or placebo at monthly intervals. They were assessed for treatment response by anal Pap smears, high-resolution anoscopy (HRA) with biopsy, and global physical assessment. Non-responders (i.e. those with persistent anal HSIL) after 12 or 24 weeks in the controlled trial were allowed to crossover to an open-label trial where they received 3 injections of 500 micro g of HspE7 at monthly intervals. The treatment assignment was double-blinded in the placebo-controlled trial, and the blind has not been broken. At the time of their entry into the open label trial, 14 of the 22 patients (64 %) had anogenital warts that had persisted throughout the prior double-blind trial in which they received 3 monthly injections of 100 micro g of HspE7 or placebo. Of the 14 patients, 8 patients (57 %) had worsened, 4 patients (29 %) had no change, and 2 patients (14 %) improved (one dramatically and the other minimally) by the time they crossed over to the open label trial. Of the 14 patients with warts at the beginning of the open label trial, the site investigator determined that surgical ablation was needed for 11 (79 %) patients, local ablation was needed for 2

patients (14 %), and topical treatment was needed for 1 patient (7 %). These patients elected to postpone the site investigator's recommended treatment, consenting instead to receive 3 injections of HspE7 500 micro g monthly intervals in the open label trial. One month after the final treatment with 500 micro g of HspE7, 2 patients (14 %) had no detectable warts, 11 patients (79 %) had a reduction in the size or number of warts as compared with their status upon entry into the open-label trial, and 1 patient (7 %) experienced an increase in wart size. By the time of the primary evaluation point of the open label trial (4 months after the final dose) one additional patient experienced an improvement from partial to complete response (i.e. no visible warts), giving a total of 3 (21 %) complete responders. None of these responders relapsed during 6 months of evaluation in the open label trial. 10 patients (71 %) continued to exhibit improvement in partial response (i.e. warts reduced further in size significantly with continued diminution of the extent of treatment needed to remove the remaining warts). The one non-responder (97 %) did not improve by the end of the open-label trial. MECHANISM OF ACTION - Vaccine. USE - (I) and (II) are useful for treating a wart, and a disease or condition associated with HPV, e.g. anogenital warts, plantars warts, cervical cancer, cervical dysplasia, anal cancer anal dysplasia, or recurrent respiratory papillomatosis. WO 200200242A

CHOSEN-DRAWING: Dwg.0/0